FORM PTO-1390 (REV 10-94)	U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY'S DOCKET NUMBER
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		9663.57USWO
		U S APPLICATION NO (If known, see 37 C F R 1 5) 10/069225

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/N000/00284	August 31, 2000	September 1, 1999

TITLE OF INVENTION

AN ACCESSORY DEVICE FOR A RESUSCITATION UNIT

APPLICANT(S) FOR DO/EO/US

Frank Lovstad

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [X] This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(l).
4. [X] A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [X] is transmitted herewith (required only if not transmitted by the International Bureau).
   b. [X] has been transmitted by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US)
6. [ ] A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. [X] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [X] are transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] have been transmitted by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [ ] have not been made and will not be made.
8. [ ] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. [X] An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. [ ] A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. [X] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [X] A FIRST preliminary amendment.
    [ ] A SECOND of SUBSEQUENT preliminary amendment.
14. [ ] A substitute specification.
15. [ ] A change of power of attorney and/or address letter.
16. [X] Other items or information: Copy of PCT/NOOO/00284, Form PCT/IPEA/402, Form PCT/IPEA/409, Form PCT/ISA/210

JC19 Rec'd PCT/PTO 21 FEB 2002

U.S. APPLICATION NO. (If known, see 37 C F R 1 5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
10/069225	PCT/NOOO/00284	9663.57USWO

17. [X] The following fees are submitted:

	CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE (37 CFR 1.492(a) (1)-(5)):		
Search Report has been prepared by the EPO or JPO **$890.00**		
International preliminary examination fee paid to USPTO (37 CFR 1.492(a)(1)) **$710.00**		
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) **$740.00**		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(3)) paid to USPTO **$1040.00**		
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) **$100.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	**$1040.00**	
Surcharge of **$130.00** for furnishing the oath or declaration later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	**$0.00**	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	2 -20 =	0	X **$18.00**	**$0.00**	
Independent claims	1 -3 =	0	X **$80.00**	**$0.00**	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$260.00**	**$0.00**	
TOTAL OF ABOVE CALCULATIONS =				**$1040.00**	
Reduction by 1/2 for filing by small entity, if applicable. Small entity status is claimed pursuant to 37 CFR 1.27				**$520.00**	
SUBTOTAL =				**$520.00**	
Processing fee of **$130.00** for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(f).			+	**$0.00**	
TOTAL NATIONAL FEE =				**$520.00**	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property			+	**$0.00**	
TOTAL FEES ENCLOSED =				**$520.00**	
				Amount to be: refunded	**$520.00**
				charged	**$0.00**

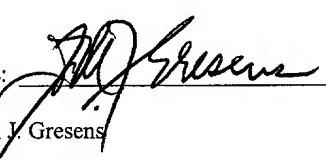
a. [X] Check(s) in the amount of $520.00 to cover the above fees is enclosed.

b. [ ] Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 13-2725.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO
John J. Gresens
MERCHANT & GOULD
P.O. Box 2903
Minneapolis, MN 55402-0903

SIGNATURE: 

NAME: John J. Gresens

REGISTRATION NUMBER: 33,112

S/N Unknown PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Frank Lovstad	Examiner:	Unknown
Serial No.:	Unknown	Group Art Unit:	Unknown
Filed:	File herewith	Docket No.:	9663.57USWO

Title: AN ACCESSORY DEVICE FOR A RESUSCITATION UNIT

CERTIFICATE UNDER 37 CFR 1.10
'Express Mail' mailing label number: EL669944289US
Date of Deposit: February 21, 2002
I hereby certify that this paper or fee is being deposited with the United States Postal Service 'Express Mail Post Office To Addressee' service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

By: Chris Stordahl

PRELIMINARY AMENDMENT

Box PCT
Assistant Commissioner for Patents
Washington, D. C. 20231

Dear Sir:

In connection with the above-identified application filed herewith, please enter the following preliminary amendment.

IN THE ABSTRACT

Insert the attached Abstract page into the application as the last page thereof.

IN THE SPECIFICATION

A courtesy copy of the present specification is enclosed herewith. However, the World Intellectual Property Office (WIPO) copy should be relied upon if it is already in the U.S. Patent Office.

REMARKS

A new abstract page is supplied to conform to that appearing on the publication page of the WIPO application, but the new Abstract is typed on a separate page as required by U.S. practice.

Applicants respectfully request that the preliminary amendment described herein be entered into the record prior to examination and consideration of the above-identified application.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' primary attorney-of record, John J. Gresens (Reg. No. 33,112), at (612) 371.5265.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Dated: February 21, 2002

By _____
John J. Gresens
Reg. No. 33,112

J. Gresens:hb

ABSTRACT

An accessory device for resuscitation unit for neonatal or premature infants for preventing baro-trauma and/or volu-trauma, and the subsequent development of broncopulmonary dysplasia, comprises a self-regulating maximum pressure/volume valve between a conventional resuscitation bag per se and its associated face mask, for blow-off of excess air volume, and having a frequency-adjustable, rhythm-indicating metronome connected thereto.

AN ACCESSORY DEVICE FOR A RESUSCITATION UNIT

The present invention relates to an accessory device for a resuscitation unit.

More precisely, the invention relates to a device for use in connection with conventional resuscitation equipment to enhance safety during the ventilation treatment of premature and neonatal infants.

Broncopulmonary dysplasia, BDP, is a highly common and dreaded complication in premature infants, i.e., infants born before term, whose lungs are not yet fully developed (surfactant deficiency, hyaline membrane syndrome, respiratory distress and so forth).

When there is surfactant deficiency, the lungs have a tendency to develop progressive atelectasis, which in turn results in the need for respirator support, often with increasing pressure support.

Often, a lung deficient in surfactants will also require ventilation by means of resuscitation equipment before the infant is placed in the respirator.

For this first phase whilst the infant is ventilated by bag, there is today no reliable control of the pressure used during the ventilation or of the gas volume with which the infant's lungs are filled.

Although the conventional resuscitation bags that are currently available have a so-called safety valve that should be released at a pressure of about 30 cm H_2O, it is known today that this does not always happen.

Studies carried out at Temple University in Philadelphia and also at the neonatal intensive care unit at Ullevål Hospital in Oslo have shown that the bags used today and which are generally available on the market, do not release the safety valve until the pressure is over 30 cm H_2O, and at ventilation of frequencies $\geq$ 80/min, release often only takes place when the pressure is $\geq$ 50 cm H_2O.

The reason that premature infants develop BPD is so-called baro-trauma and/or volu-trauma, i.e., that both the pressure and the volume used are greater than the lungs of the smallest premature infants can withstand. Today, there is much to suggest that the infant suffers these traumas as early as in the delivery ward, or perhaps in the operating

theatre if delivery by Caesarean section is required, when the infant is in need of resuscitation.

Over the years a great number of publications have appeared, including some from the aforementioned medical centres, that stress the importance of reducing baro-trauma in the neonatal period in order to prevent chronic lung disease. It is believed that this problem affects about 37% of small, premature infants that have recovered after severe respiratory distress syndrome at birth.

Today, therefore, efforts are being made to minimise the pressure exposure to which infants are subjected in all phases of neonatal treatment.

Consequently, there is an explicit need among those wishing to make the treatment, including resuscitation, of premature and neonatal infants, as safe as possible, and therefore a device is required that can be used together with today's conventional resuscitation bags to safeguard against baro-trauma and volu-trauma by reacting both quickly and reliably when predetermined maximum values are exceeded.

The object of the present invention is to remedy the deficiencies of the prior art, and the invention is in principle based on the following ideas.

Today, in the resuscitation of neonatal or premature infants, a manual ventilation bag is used. In premature births from 24 weeks of gestation to 36 weeks inclusive, the infant's airways, as mentioned above, are not fully developed, and these infants, who cannot yet breathe unaided, will be hand-ventilated with a ventilation bag in the first important minutes after birth.

Because the airways, as already mentioned, are not fully developed, they are also extremely sensitive as they lack the essential elasticity, primarily because the natural surface-active agents, surfactants, which contribute greatly to the elasticity are lacking.

It is a fact that in today's means for immediate hand ventilation, there is no full control of the pressure, volumes and frequencies that are used. When an infant in such a situation does not breathe, the staff often lose their sense of time to a certain degree, even highly experienced staff. This may unconsciously result in an excessively high ventilation frequency.

Depending somewhat on local routines, a mechanical manometer may be connected to measure the pressure with which the newborn infant is ventilated.

The pressure is measured at the connection between the bag and the face mask.

However, the problem with this technology is that the manometers used do not react anywhere near quickly enough, and therefore the medical personnel have no true picture of the pressure that in fact prevails.

If a faster reacting digital pressure recorder is connected, a substantially higher pressure will be seen when the frequency rises.

However, there is also no limit on the pressure if the staff are a little careless or inexperienced and may thus inadvertently ventilate using an excessively high pressure.

Lastly, there is no control as regards the volume delivered. Here it should be remembered that the volumes involved are as little as 2 to 3 ml.

On today's market there are pressure relief valves that can be fitted on the ventilation bag. These are mechanical spring valves which have a very poor frequency response, i.e., in the first place, they are highly inaccurate as regards the pressure and, in the second place, the pressure released increases at frequencies above 40/min.

On account of these factors as they are summarised above, there have been cases of ventilation frequencies as high as 120/min.

All these factors separately and, of course, even more so in combination, will result in hyperventilation (an overstretching of the infant's airways). If there is such an overstretching of the rather inelastic parts of the airways, these extremely small airways (alveoli) will not return to their original form but will instead pass into a plastic state, which at worst can result in death, and at best can result in the child remaining in a respirator for days, weeks or even months.

As mentioned above, it is therefore an express wish among those who work with premature and neonatal infants to have at their disposal a simple product that in a simple manner limits the pressure and volume and which at the same time gives clear indications as regards the ventilation frequency that is to be used.

Thus, the object of the present invention is to develop a device this kind that also should be capable of being connected promptly and readily to existing resuscitation equipment.

The idea behind the present invention is to develop a simple monitor that registers and regulates the pressure and volume of air that is given to premature infants by hand ventilation. This monitor must have an external sensor that is connected to the manual ventilation bag (or the bellows) used, between the bag and the face mask.

When the volume or the pressure reaches a given value the device should "blow off" the excess.

One way of doing this is to work with an electromagnetic pressure control valve.

Advantageously, the valve is self-regulating, i.e., just one signal to the valve will be sufficient to ensure that it carries out the required control.

Accordingly, the present invention relates to an accessory device for a unit for the resuscitation of newborn or premature infants for the purpose of preventing baro-trauma and/or volu-trauma and the subsequent development of broncopulmonary dysplasia, and this device is characterised by a self-regulating maximum pressure/volume valve between conventional resuscitation equipment per se and the associated face mask, or endotracheal tube (ET Tube), for blow-off of excess air volume, and having a frequency-adjustable, rhythm-indicating metronome connected thereto.

The invention will be explained in more detail with the use of the attached figures, wherein:

- Figure 1 is a block diagram of the electronic limitation of hand ventilation;
- Figure 2 is an outline of an embodiment of the pathway for the electronic signals;
- Figure 3 is a schematic diagram of an electromagnetic pressure/flow control valve; and
- Figure 4 shows what a control box may look like.

In the figures the letters MCU stand for "Micro Control Unit". In Figure 2 the letters BPM stand for the breathing frequency "Breath per Minute".

The inventive idea is based on the principle of installing a control box that is to measure flow and pressure and on the basis thereof compute inhaled volume and pressure. When the correct volumes or pressures have been reached, the operating pressure is to be reduced so that inspiration is terminated.

As mentioned above, this is intended as a complement to the known manual ventilation equipment for premature and neonatal patients, as premature infants have a special need for accurate control of the ventilation in order to prevent the damage outlined above from occurring.

In principle, it is possible to use any rapid-action, self-regulating electronically operated valve, but in a preferred embodiment electromagnetism is used as an actuating force on a magnetically sensitive object to enable the object to close a flow path with desired force and thus be able to control the flow therethrough. As mentioned, it is desirable that the valve should be self-regulating, i.e., that just one signal should be sufficient to enable it to carry out its control functions.

It is also possible to use a solenoid valve.

The control box, as indicated in Figure 4, contains a micro-processor that processes the signals it receives from a flow sensor and a pressure sensor. The user himself must define the desired pressure and volume limits within a restricted range, as the conditions must be established instantly, according to all the circumstances of the birth. The received signals then control the further processing of the signals by the micro-processor.

As mentioned above, frequency plays a very important role, and within the given circumstances surrounding the birth it should be possible to pre-set, for example, at most three frequencies which then must be observed during the subsequent hand ventilation.

Fig. 1 shows in general the units required to be able to replace an existing bag valve with a valve belonging to the device according to the invention.

Volume and pressure are monitored and maintained against set pressure and volume at the same time as the selected frequency is given.

Figure 2 shows in slightly greater detail a possible connection to the computer unit where the signals are processed. Outgoing signals are also indicated in the drawing.

Figure 3 shows a possible embodiment of a valve in the device according to the invention. Flow C under a pressure P1 acts against a closing body D with force A whilst the element D is held in the valve V by means of an applied magnetic field.

Lastly, Figure 4 shows, as mentioned above, a control box which in addition to pressure also contains a setting means for desired ventilation frequency and volume based on the given body weight and in which also flow sensor signals enter.

The box is also equipped with a form of frequency indicator, for example, by using a loudspeaker and/or light emitting diode as shown in the figure.

Broadly speaking, the device consists of two parts, a flow sensor and a control box with equipped with a pressure sensor and control buttons for setting the desired tidal volume, frequency and pressure.

The frequency is to be indicated by a "metronome" or pacer that provides the user with sounds (ticks) and light signals (diode). It is important that there are few frequency choices, for example, 30-60-80.

Volume can be set either by choosing, with the use of a control button, the body weight of the patient, and in so doing be given a pre-programmed volume/kg (for example, 5 ml/kg), or by choosing a number ml tidal volume directly as a value. The last alternative is perhaps the most useful because the first alternative substantially limits the area of application of the equipment.

Maximum inspiratory pressure is selected by means of a separate control button. The selected maximum pressure should then be guiding for the control of the regulator.

Pressure and volume should be equally important controlling parameters (that reached first).

By means of the inventive accessory device, it will be possible to greatly enhance safety during hand ventilation of neonatal and premature infants.

The device is easy to make, and it can be varied according to the circumstances surrounding the birth. It will provide a rapid reaction and contain few details that can be harmed or destroyed.

An essential feature is that the device can be connected to all hand ventilation bags in existence today as devices of this kind have standard connection units.

A major advantage is that the equipment is easy to use and that it is inexpensive to procure and easy to maintain.

Patent claim

An accessory device for a resuscitation unit for neonatal or premature infants for preventing baro-trauma and/or volu-trauma and the subsequent development of broncopulmonary dysplasia, characterised by a self-regulating maximum pressure/volume valve between conventional resuscitation equipment per se and its associated face mask, or endotracheal tube (ET Tube), for blow-off of excess air volume, and having a frequency-adjustable, rhythm-indicating metronome connected thereto.

AMENDED CLAIMS

[received by the International Bureau on 17 January 2001 (17.01.01);
original claim 1 replaced by new claims 1 - 2 (1 page)]

1

Hand held, portable accessory device for a manual resuscitation unit for neonatal or premature infants with presice control of manual generated low tidal volumes and calculation of the compliance of the lungs for preventing volutrauma and/or barotrauma in connection with the resuscitation in the first phase of life, c h a r a c t e r i z e d b y a self regulating maximum pressure/volume valve connected to a per se conventional resuscitation equipment for blow off of excess air.

2.

Device according to claim 1 consisting of
a portable, battery driven control unit for input of maximum values for pressure or volume,
a rhythm indicating unit with the rhythm indicated through sound and light signals,
a display in the control unit which electronically is giving the ratio between pressure and tidal volume (lunge compliance),
a flow sensor for measuring pressure and air flow, giving signals to the control unit,
an electronic valve actuator for presice and rapid response for blowing off excess volume and pressure of air.

BLOCK DIAGRAM

ACCESSORY DEVICE FOR ELECTRONIC LIMITATION OF HAND VENTILATION

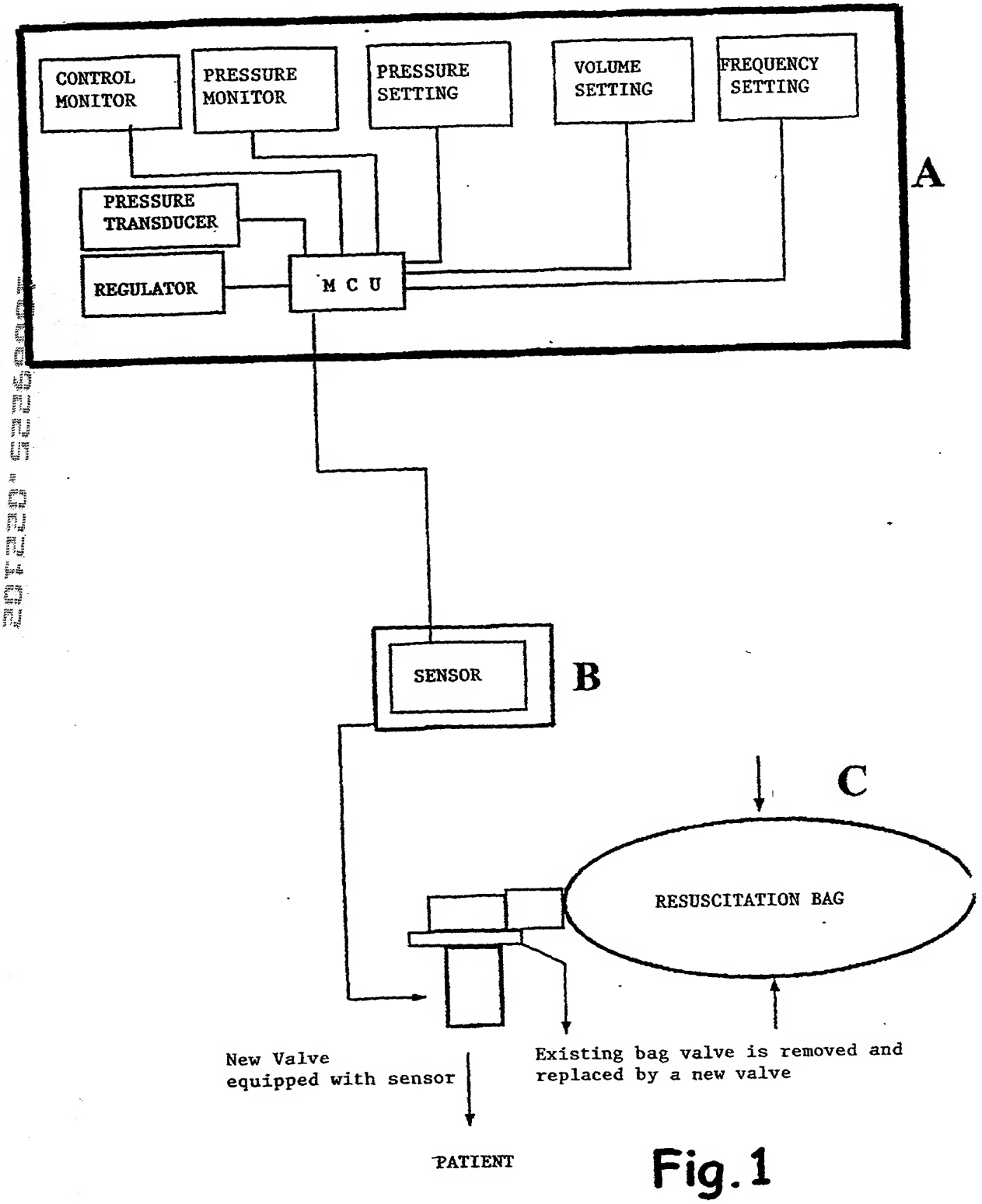


Fig.1

Inventor: Frank Lovstad
Docket No.: 9663.57USWO
Title: AN ACCESSORY DEVICE FOR A RESUSCITATION UNIT
Attorney Name: John J. Gresens
Phone No.: 612 371.5265
Sheet 2 of 4

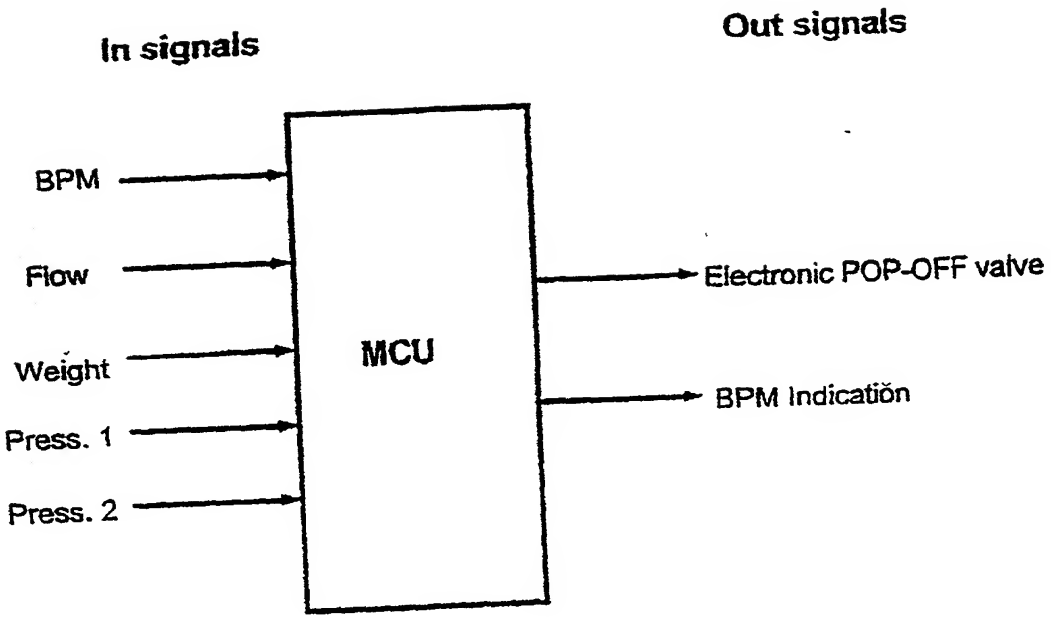
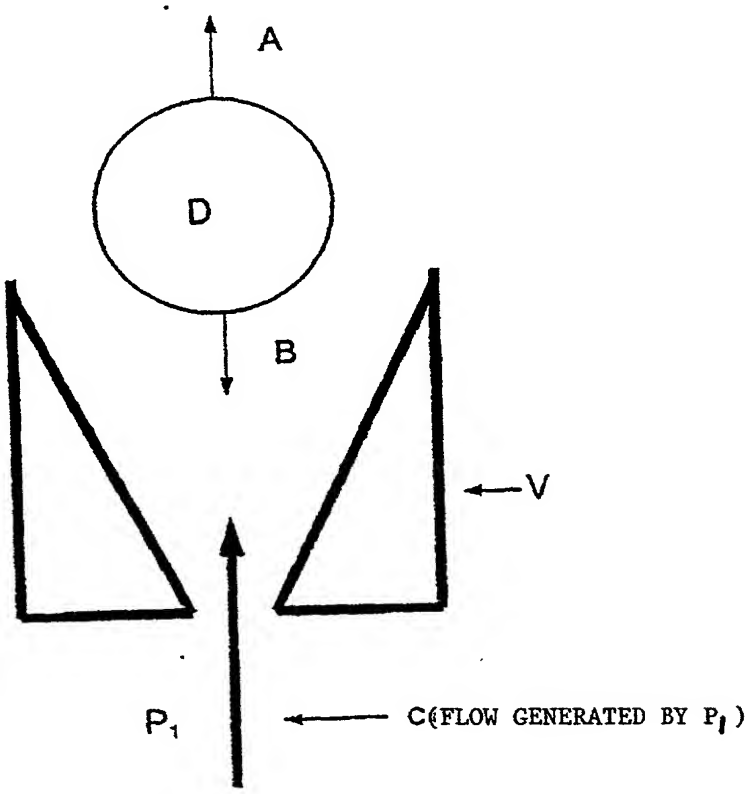


Fig.2

SCHEMATIC DIAGRAM OF ELECTROMAGNETIC CONTROL OF PRESSURE/FLOW, HAND VENTILATION - PREMATURE



P_1 = PRESSURE TO BE CONTROLLED

A = FORCE ACTING ON D BECAUSE OF C

B = FORCE ACTING ON D BECAUSE OF MAGNETIC FIELD

Fig.3

Inventor: Frank Lovstad
Docket No.: 9663.57USWO
Title: AN ACCESSORY DEVICE FOR A RESUSCITATION UNIT
Attorney Name: John J. Gresens
Phone No.: 612.371.5265
Sheet 4 of 4

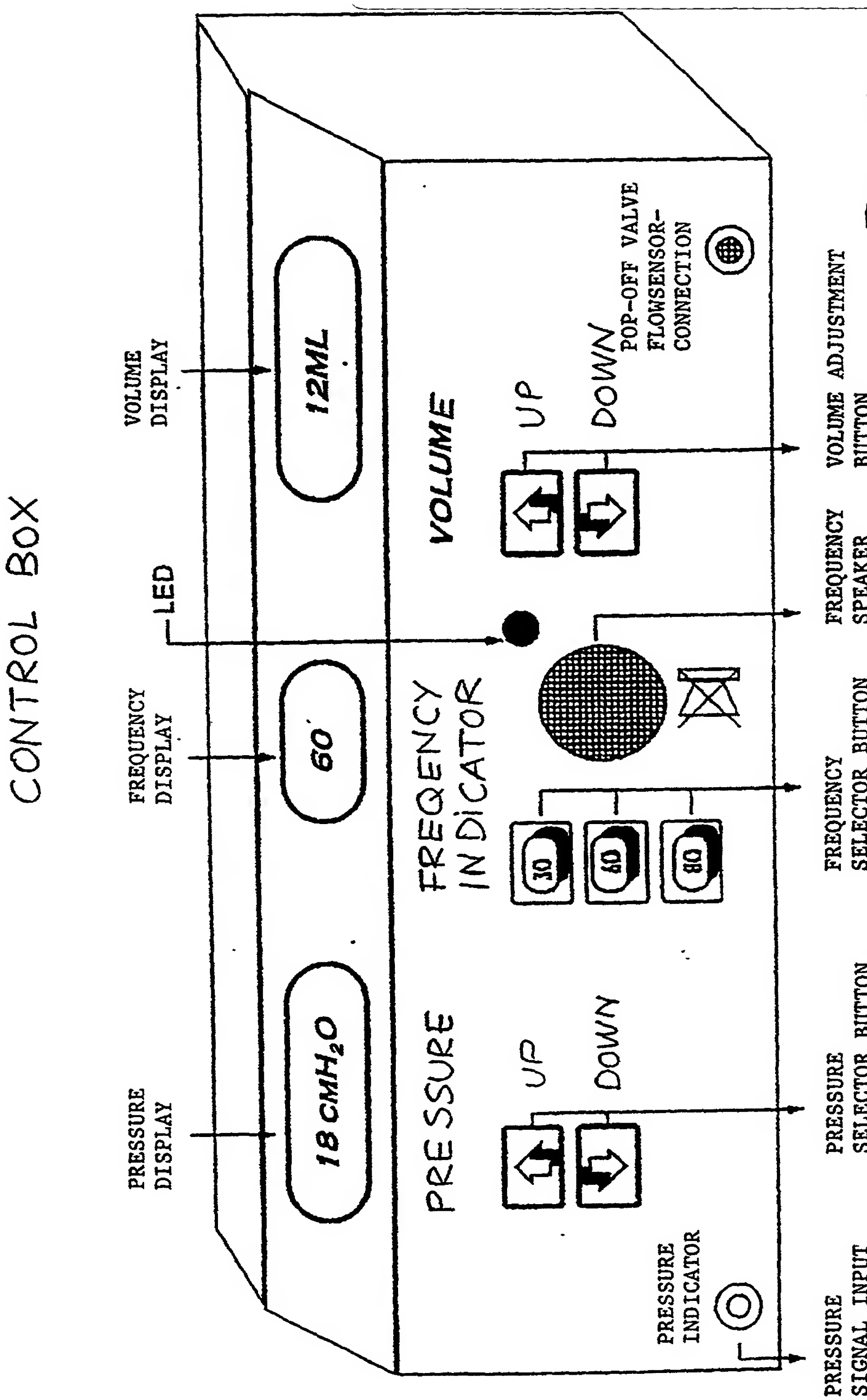


Fig.4

For Utility, PCT, and Design Applications

▼ INSTRUCTIONS

MERCHANT & GOULD

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Insert TITLE of invention

AN ACCESSORY DEVICE FOR A RESUSCITATION UNIT

Check a or b

The specification of which

a. ☐ is attached hereto

b. ☐ was filed on _____

If "b" checked, complete

as application serial no. _____

and was amended on _____ (if applicable)

If PCT Application

(in the case of PCT-filed application)

Insert Int. application number & filing date

described and claimed in international no. PCT/NO00/00284 filed 31 August 2000

and as amended on 17.01.01 (if any), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56(a). (Reprinted on back side).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119/365 of any foreign application(s) for patent of inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

Prior applications Check a or b

a. ☐ no such applications have been filed.

b. ☒ such applications have been filed as follows:

If "b" checked, complete

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC § 119			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)
NORWAY	19994230	01.09.1999	
ALL FOREIGN APPLICATIONS, IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)

I hereby claim the benefit under Title 35, United States Code, § 120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

For Continuation-in-Part (CIP) Applications, complete

U.S. APPLICATION NUMBER	DATE OF FILING (day,month,year)	STATUS (patented,pending,abandoned)

I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Adriano, Sarah B.	Reg. No. 34,470	Gabilan, Mary Susan	Reg. No. 38,729	Nelson, Albin J.	Reg. No. 28,650
Batzli, Brian H.	Reg. No. 32,960	Gates, George H.	Reg. No. 33,500	Pauly, Daniel M.	Reg. No. 40,123
Beard, John L.	Reg. No. 27,612	Golla, Charles E.	Reg. No. 26,896	Plunkett, Theodore	Reg. No. 37,209
Beck, Robert C.	Reg. No. 28,184	Gorman, Alan G.	Reg. No. 38,472	Pollinger, Steven J.	Reg. No. 35,326
Bejin, Thomas E	Reg. No. 37,089	Gould, John D.	Reg. No. 18,223	Reich, John C.	Reg. No. 37,703
Berman, Charles	Reg. No. 29,249	Gresens, John J.	Reg. No. 33,112	Reiland, Earl D.	Reg. No. 25,767
Bogucki, Raymond A.	Reg. No. 17,426	Hamre, Curtis B.	Reg. No. 29,165	Schmaltz, David G.	Reg. No. 39,828
Bruess, Steven C.	Reg. No. 34,130	Hillson, Randall A.	Reg. No. 31,838	Schmidt, Cecil C.	Reg. No. 20,566
Byrne, Linda M.	Reg. No. 32,404	Hollingsworth, Mark A.	Reg. No. 38,491	Schuman, Mark D.	Reg. No. 31,197
Carlson, Alan G.	Reg. No. 25,959	Johnston, Scott W.	Reg. No. 39,721	Schumann, Michael D.	Reg. No. 30,422
Carter, Charles G.	Reg. No. 35,093	Kastelic, Joseph M.	Reg. No. 37,160	Sebald, Gregory A.	Reg. No. 33,280
Caspers, Philip P	Reg. No. 33,227	Kettelberger, Denise	Reg. No. 33,924	Sharp, Janice A.	Reg. No. 34,051
Chiapetta, James R.	Reg. No. 39,634	Kowalchyk, Alan W.	Reg. No. 31,535	Skoog, Mark T.	Reg. No. 40,178
Clifford, John A.	Reg. No. 30,247	Kowalchyk,Katherine M.	Reg. No. 36,848	Smith, Jerome R.	Reg. No. 35,684
Conrad, Timothy R	Reg. No. 30,164	Krull, Mark A.	Reg. No. 34,205	Stinebruner, Scott A.	Reg. No. 38,323
Cooper, Victor G.	Reg. No. 39,641	Lacy, Paul A.	Reg. No. 38,946	Sumner, John P.	Reg. No. 29,114
Crawford, Robert	Reg. No. 32,122	Lasky, Michael B.	Reg. No. 29,555	Sumners, John S.	Reg. No. 24,216
Daignault, Ronald A.	Reg. No. 25,968	Lynch, David W.	Reg. No. 36,204	Tellekson, David K.	Reg. No. 32,314
Daley, Dennis R.	Reg No. 34,994	Mau, Michael L.	Reg. No. 30,087	Underhill, Albert L.	Reg. No. 27,403
Daulton, Julie R.	Reg. No. 36,414	McCormack, Myra H.	Reg. No. 36,602	Vandenburgh, J. Derek	Reg. No. 32,179
Davidson, Ben M.	Reg. No. 38,424	McDaniel, Karen D.	Reg. No. 37,674	Welter, Paul A.	Reg. No. 20,890
Dempster, Shawn B.	Reg. No. 34,321	McDonald, Daniel W.	Reg. No. 32,044	Williams, Douglas J.	Reg. No. 27,054
DiPietro, Mark J.	Reg. No. 28,707	McDonald, Wendy M.	Reg. No. 32,427	Wood, Gregory B.	Reg. No. 28,133
Edell, Robert T.	Reg. No. 20,187	Miller, William D.	Reg. No. 37,988	Xu, Min S.	Reg. No. 39,536
Farber, Michael B.	Reg. No. 32,612	Mueller, Douglas P.	Reg. No. 30,300		
Funk, Steven R.	Reg. No. 37,830	Nasiedlak, Tyler L.	Reg. No. 40,099		

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/organization/who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Merchant & Gould to the contrary.

Please direct all correspondence in this case to Merchant, Gould, Smith, Edell, Welter & Schmidt at the address indicated below (or if no address is specified, the first address):

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Telephone No. (612) 332-5300

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Telephone No. (612) 298-1055

☐ Suite 400, 11150 Santa Monica Boulevard, Los Angeles, CA 90025-3302
Telephone No. (310) 445-1140

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Insert FULL name(s) AND address(es) of actual inventor(s)

202	FULL NAME OF INVENTOR	FAMILY NAME: LØVSTAD	FIRST GIVEN NAME: Frank	SECOND GIVEN NAME:
	RESIDENCE & CITIZENSHIP	CITY: TOLVSRØD	STATE OR FOREIGN COUNTRY: Norway	COUNTRY OF CITIZENSHIP: Norway
	POST OFFICE ADDRESS	POST OFFICE ADDRESS: Valløveien 74B	CITY: TOLVSRØD	STATE & ZIP CODE/COUNTRY: N-3150 NORWAY
202	FULL NAME OF INVENTOR	FAMILY NAME:	FIRST GIVEN NAME:	SECOND GIVEN NAME:
	RESIDENCE & CITIZENSHIP	CITY:	STATE OR FOREIGN COUNTRY:	COUNTRY OF CITIZENSHIP:
	POST OFFICE ADDRESS	POST OFFICE ADDRESS:	CITY:	STATE & ZIP CODE/COUNTRY:
203	FULL NAME OF INVENTOR	FAMILY NAME:	FIRST GIVEN NAME:	SECOND GIVEN NAME:
	RESIDENCE & CITIZENSHIP	CITY:	STATE OR FOREIGN COUNTRY:	COUNTRY OF CITIZENSHIP:
	POST OFFICE ADDRESS	POST OFFICE ADDRESS:	CITY:	STATE & ZIP CODE/COUNTRY:

SIGNATURE OF INVENTOR 201	SIGNATURE OF INVENTOR 202	SIGNATURE OF INVENTOR 203
DATE 24/10-01	DATE	DATE

Each inventor must sign & date

Note: No legalization or other witness required

Revised 12/6/95

For Additional Inventors:

☐ Check box and attach sheet with same information, including date and signature.

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by § 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.